



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,592	08/17/2005	Ronald Rodriguez	58799(71699)	9269
21874 7590 02/12/2008 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205				
EXAMINER				
WHITEMAN, BRIAN A				
ART UNIT		PAPER NUMBER		
1635				
MAIL DATE		DELIVERY MODE		
02/12/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No. 10/510,592	Applicant(s) RODRIGUEZ ET AL.
Examiner BRIAN WHITEMAN	Art Unit 1635

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 January 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 25 January 2008. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
b) ☐ They raise the issue of new matter (see NOTE below);
c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): 112 first paragraph written description.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: None.
Claim(s) objected to: None.
Claim(s) rejected: 16, 19, 20, 22-34, 38.
Claim(s) withdrawn from consideration: None.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Brian Whiteman/
Primary Examiner, Art Unit 1635

Continuation of 11. does NOT place the application in condition for allowance because: In response to applicant's argument that there is no requirement that applicant provide data for every therapeutic method (See *Amgen v. Chugai and Genetic Institute*) and it is well established that examples are not required for an enabling disclosure, the argument is not found persuasive because while it is acknowledged that not every therapeutic method be provided nor examples for enabling disclosure, this does not apply here because those arguments are based on the method being routine to one of skill in the art. However, using a genus of administration routes to deliver adenovirus to target site (tumor) in a subject is not considered routine by one of skill in the art. See *McNeish and Vile* (of record). Furthermore, the skilled artisan understands that systemic delivery of adenovirus results in the majority, if not all of the adenovirus being delivered to the liver.

In response to applicant's argument that to date there are dozen of clinical trials in the U.S. and many more around the world that involve gene therapy and while failures may occur it is important to consider that successes have occurred in the field of gene therapy, the argument is not considered persuasive because while, it is acknowledged that other types of gene therapies have been cited in the art as treating a particular disease or genetic disorder using distinct material and methods, the art of record teaches that one skilled in the art can not reasonably extrapolate from one type of gene therapy to another type of gene therapy without an undue amount of experimentation and the art of record teaches that there is no universal protocol that can be reasonably extrapolated from one type of gene therapy to the claimed gene therapy method. See *Genentech Inc. v. Novo Nordisk A/S* 108 F.3d 1361, 42, USPQ2s 1001, 1005 (Fed. Cir. 1997).

The exhibits (abstract and journal articles) cited on pages 7 and 8 of applicant's argument were not considered because applicant failed to provide a good and sufficient reason why the exhibits were not presented earlier and several of the exhibits are not of record. See 37 CFR 1.116(e).